

## § 172.804

20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(1) Assay for advantame, not less than 97.0 percent and not more than 102.0 percent on a dry basis.

(2) Free *N*-[*N*-[3-(3-hydroxy-4-methoxyphenyl)propyl]- $\alpha$ -aspartyl]-L-phenylalanine, not more than 1.0 percent.

(3) Total other related substances, not more than 1.5 percent.

(4) Lead, not more than 1.0 milligram per kilogram.

(5) Water, not more than 5.0 percent.

(6) Residue on ignition, not more than 0.2 percent.

(7) Specific rotation, determined at 20 °C [ $\alpha$ ]<sub>D</sub>: -45.0 to -38.0° calculated on a dry basis.

(c) The food additive advantame may be safely used as a sweetening agent and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice, in an amount not to exceed that reasonably required to achieve the intended technical effect, in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(d) If the food containing the additive purports to be or is represented to be for special dietary use, it must be labeled in compliance with part 105 of this chapter.

[79 FR 29085, May 21, 2014]

## § 172.804 Aspartame.

The food additive aspartame may be safely used in food in accordance with good manufacturing practice as a sweetening agent and a flavor enhancer in foods for which standards of identity established under section 401 of the act do not preclude such use under the following conditions:

(a) Aspartame is the chemical 1-methyl *N*-L- $\alpha$ -aspartyl-L-phenylalanine (C<sub>14</sub>H<sub>18</sub>N<sub>2</sub>O<sub>5</sub>).

(b) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 73-74, which is incorporated by reference. The Director of

## 21 CFR Ch. I (4-1-19 Edition)

the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(c)(1) When aspartame is used as a sugar substitute tablet for sweetening hot beverages, including coffee and tea, L-leucine may be used as a lubricant in the manufacture of such tablets at a level not to exceed 3.5 percent of the weight of the tablet.

(2) When aspartame is used in baked goods and baking mixes, the amount of the additive is not to exceed 0.5 percent by weight of ready-to-bake products or of finished formulations prior to baking. Generally recognized as safe (GRAS) ingredients or food additives approved for use in baked goods shall be used in combination with aspartame to ensure its functionality as a sweetener in the final baked product. The level of aspartame used in these products is determined by an analytical method entitled "Analytical Method for the Determination of Aspartame and Diketopiperazine in Baked Goods and Baking Mixes," October 8, 1992, which was developed by the Nutrasweet Co. Copies are available from the Office of Premarket Approval (HFS-200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or are available for inspection at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/](http://www.archives.gov/federal_register/)

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*ibr\_locations.html*.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The principal display panel of any intermediate mix of the additive for manufacturing purposes shall bear a statement of the concentration of the additive contained therein;

(2) The label of any food containing the additive shall bear, either on the principal display panel or on the information panel, the following statement:

PHENYLKETONURICS: CONTAINS  
PHENYLALANINE

The statement shall appear in the labeling prominently and conspicuously as compared to other words, statements, designs or devices and in bold type and on clear contrasting background in order to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(3) When the additive is used in a sugar substitute for table use, its label shall bear instructions not to use in cooking or baking.

(4) Packages of the dry, free-flowing additive shall prominently display the sweetening equivalence in teaspoons of sugar.

(e) If the food containing the additive purports to be or is represented for special dietary uses, it shall be labeled in compliance with part 105 of this chapter.

[39 FR 27319, July 26, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 172.804, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.govinfo.gov](http://www.govinfo.gov).

#### § 172.806 Azodicarbonamide.

The food additive azodicarbonamide may be safely used in food in accordance with the following prescribed conditions:

(a) It is used or intended for use:

(1) As an aging and bleaching ingredient in cereal flour in an amount not to exceed 2.05 grams per 100 pounds of flour (0.0045 percent; 45 parts per million).

(2) As a dough conditioner in bread baking in a total amount not to exceed

0.0045 percent (45 parts per million) by weight of the flour used, including any quantity of azodicarbonamide added to flour in accordance with paragraph (a)(1) of this section.

(b) To assure safe use of the additive:

(1) The label and labeling of the additive and any intermediate premix prepared therefrom shall bear, in addition to the other information required by the Act, the following:

(i) The name of the additive.

(ii) A statement of the concentration or the strength of the additive in any intermediate premixes.

(2) The label or labeling of the food additive shall also bear adequate directions for use.

#### § 172.808 Copolymer condensates of ethylene oxide and propylene oxide.

Copolymer condensates of ethylene oxide and propylene oxide may be safely used in food under the following prescribed conditions:

(a) The additive consists of one of the following:

(1)  $\alpha$ -Hydro-*omega*-hydroxy-poly (oxyethylene) poly(oxypropylene)-(55-61 moles)poly(oxyethylene) block copolymer, having a molecular weight range of 9,760-13,200 and a cloud point above 100 °C in 1 percent aqueous solution.

(2)  $\alpha$ -Hydro-*omega*-hydroxy-poly (oxyethylene)poly(oxypropylene)-(53-59 moles)poly(oxyethylene)(14-16 moles) block copolymer, having a molecular weight range of 3,500-4,125 and a cloud point of 9 °C-12 °C in 10 percent aqueous solution.

(3)  $\alpha$ -Hydro-*omega*-hydroxy-poly(oxyethylene)/poly(oxypropylene) (minimum 15 moles)/poly(oxyethylene) block copolymer, having a minimum average molecular weight of 1900 and a minimum cloud point of 9 °C-12 °C in 10 percent aqueous solution.

(4)  $\alpha$ -Hydro-*omega*-hydroxy-poly(oxyethylene) poly (oxypropylene)-(51-57 moles) poly(oxyethylene) block copolymer, having an average molecular weight of 14,000 and a cloud point above 100 °C in 1 percent aqueous solution.

(b) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a)(1) of this section is used in practice as a solubilizing and stabilizing agent in flavor concentrates